

Policy & Procedure (P&P)

Policy Title :

DAILY REAGENT QUALITY CONTROL

Department	Index No.	Scope
Laboratory & Blood Bank	LAB-069	All Blood Bank staff
Issue Date	Revision NO	Effective Date
1433/06/10	2	1440/08/14
Review Due Date	Related Standard NO.	Page Number#
1442/08/14	CBAHI (LB.61)	14

01. Policy:

The blood bank confirms that each reagent, on each day of use, is suitably reactive when used according to the manufacturer's instructions.

02. Definition :

QC: quality control

03. Purpose :

To confirm the reliability of the test system on each day of use. The results of the quality control performed on the reagents and antisera must demonstrate acceptable performance before patient tests results are released. If expected tests results are observed, procedures are being performed accurately and reagents and equipment are performing properly.

04. Procedure :

Some principles are common for all the quality controls used in blood bank:

- 04.1. Antisera are checked against known positive and negative cells.
- 04.2. Red blood cells reagents are checked against known positive and negative antisera.
- 04.3. The results are checked against predefined acceptable results.
- 04.4. The results are reviewed and reagents are approved before use for patient testing.
- 04.5. Corrective actions are taken for unacceptable results.

Upon Receipt: Perform a visual inspection of all reagents upon receipt in the Transfusion Medicine Laboratory:

1 Reagents red cells: Each vial of red cells received should be allowed to settle and then visually inspected for hemolysis or discoloration.

2 Antisera: a representative sample of the antisera must be visually inspected for cloudiness, turbidity and/or particulate matter.

3 Potentiators: Each vial received must be visually inspected for cloudiness, turbidity and/or particulate matter.

Daily Quality Control (QC):

Perform daily QC using commercial QC system and prior to performing daily QC testing, perform visual inspection of reagents and anti-sera.

I. DAILY QC OF SEROLOGICAL BLOOD BANK REAGENTS: TUBE METHOD

1. Materials:

1. 1. Calibrated Centrifuge.
1. 2. Glass test tubes.
1. 3. Calibrated Blood Bank pipettes

2. Reagents:

2. 1. Blood grouping serum anti-A
2. 2. Blood grouping serum anti-B
2. 3. Blood grouping serum anti-AB if available
2. 4. Blood grouping serum anti-D
2. 5. Rh Control
2. 6. Anti-A1 lectin
2. 7. Albumin
2. 8. Antihuman globulin
2. 9. Reagent red cells A1
2. 10. Reagent red cells B
2. 11. Reagent Red Blood Cells, Screening Cells I

2. 12. Reagent Red Blood Cells, Screening Cells II
2. 13. Reagent Red Blood Cells screening cells III
2. 14. Coombs control cells
2. 15. Isotonic saline solution

3. Document:

1. Reagent lot number.
2. Reagent appearance.
3. Date of receipt.
4. Results of the visual inspection.
5. Name of the technologists performing the inspection.

☐ ☐ Reagents that do not meet visual inspection must not be used for testing.

Quarantine shipment until the cause has been identified and corrected.

4. Method:

- 4.1. Label test tubes 1-29 and place in rack according to the diagram.
- 4.2. Add two drops of anti-A to the appropriate tubes according to the diagram. Likewise, add one drop of anti-B, anti-AB, and anti-A1 lectin to the appropriate tubes.
- 4.3. Add two drops of anti-D, Rh Control, albumin and antihuman globulin to the appropriate tubes.
- 4.4. Add one drop of each of the cell suspensions to the appropriate tubes according to the diagram.
- 4.5. Centrifuge all tubes from 1-29 after proper mixing according to the optimum spin time listed for the centrifuge.
- 4.6. Resuspend the cells by gentle agitation and examine macroscopically for agglutination against a well-lighted background.
- 4.7. Record the results on the daily quality control sheet.
- 4.8. Incubate the following tubes for 30 minutes at 37°C: Number 5,6,11,12,17,18 if negative cell suspension is used. Also incubate number 19,20,21,22,23,24,25,26,27.
- 4.9. When the 37°C incubation is complete centrifuge the tubes according to the optimum spin time for centrifuge. Examine microscopically for agglutination and record results.

- 4.10. Wash all cells that were incubated with isotonic saline
- 4.11. To each tube add two drops of antihuman globulin.
- 4.12. Mix and centrifuge according to the optimum AHG spin time for the centrifuge.
- 4.13. Resuspend the cells by gentle agitation and examine macroscopically for agglutination against a well-lighted background.
- 4.14. If the test is negative, add known IgG sensitized cells, (coombs control cells). Centrifuge and observe for agglutination. These cells must agglutinate for a negative test result to be valid.
- 4.15. Record results on the daily quality control sheet.
- 4.16. Check that all the results correspond with what is expected i.e if screening cell I and II are positive for anti-D and screening cell III is negative for anti-D then tube 19,20 should have agglutination and tube 21 should be negative.
- 4.17. Also, if any of screening cells I,II,III are positive for the used antisera. there should be agglutination and no agglutination if the cells are negative.
- 4.18. Record the manufacturer, lot number and expiration date of each antisera and reagent red blood cells used on the daily quality control.

II- ID-GEL INTERNAL QUALITY CONTROL

There are two types of QC reagents:

- ID-internal quality control
- DiaMed Basic QC

II-1- ID-internal quality control

1- Materials

- ID-internal quality control that contains:

5 vials of 4 ml human red cell reagent from single donor as a 3-5% suspension in a buffered medium

Red cell reagent 1 (cell 1)	AB , Rh D positive
Red cell reagent 2 (cell 2)	O, Rh D negative
Red cell reagent 3 (cell 3)	O , Kell positive, R1R1

Red cell reagent 4 (cell 4)	O , Rh D weak
Red cell reagent 5 (cell 5)	DAT positive

3 vials with 3ml serum of human origin (all reagent containing bovine albumin)

Serum 1	Group AB with irregular antibody
Serum 2	Group O with irregular antibody
Serum 3	Group O without irregular antibody

2- Steps

2.1. ID Cards:

- Do not use cards that show signs of drying. A liquid layer should appear on top of the gel in each microtube.
- Do not use cards in which the microtubes show discoloration, bubbles or crystals.
- To confirm the specificity and reactivity of the IgG gel card the manufacturer recommends that each lot be tested each day of use with known positive and negative antibody samples with the appropriate red cell. Reactivity shall be present in the positive specimen only.

2.2. Red Cell reagent

- take the required vial of test cell reagents and gently resuspend the cells
- Transfer at least 500 ul to a centrifuge tube
- Centrifuge the tube for 1 minute at 3000 rpm
- decant the supernatant
- form the packed cell, make a cell suspension in ID-Diluent 1 or 2 as appropriate, according to the ID-card being used for the patient test procedure.

2.3. Quality control sera

- Ready to use for reverse grouping, for antibody screening and antibody identification
- Use the QC samples in the same manner as patient samples in routine work.

2.4. Interpretation of the results:

- Compare the reactions and the results obtained with those in the table below
- If the reactions results do not correspond to those of the table, the working procedures should be verified along with routine test methods and materials used.
- The necessary corrective action should be taken and the tests repeated.

BLOOD GROUP DETERMINATION

RESULTS			A	B	AB	D	CD E	ct l	C	C w	c	E	e	K	DAT
Ce ll 1	A B	CCDee	+	+	+	+	+	-	+	-	-	-	+	-	-
Ce ll 2	O	ccddee	-	-	-	-	-	-	-	-	+	-	+	-	-
Ce ll 3	O	CcDEe K+	-	-	-	+	+	-	+	-	+	+	+	+	-
Ce ll 4	O	ccDweak Ee	-	-	-	Weark k+	+	-	-	-	+	+	+	-	-
Ce ll 5	O	DAT +	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	Weark k+

Nt : not tested

REVERSE GROUPING

Results		A1	A2	B	O	BLOOD GROUP
	Serum 1	-	-	-	-	AB

Positive, if the corresponding Ag is present	Serum 2	+	+	+	-	O
	Serum 3	+	+	+	-	O

Antibody screening

method	Serum1 with antibody	Serum2 with antibody	Serum3 without antibody
IAT	Positive, anti Fya	Positive, anti E	negative

II-2- DiaMed Basic QC

The DiaMed Basic QC contains two types of sample tubes: sample 1 and sample 2

RESULTS			A	B	AB	D	CD E	ct l	C	C w	c	E	e	K	IAT	DAT
1	A neg	ccddee	+	-	+	-	-	-	-	-	+	-	+	+	+ anti D	-
2	B +	CcDEe	-	+	+	+	+	-	+	-	+	+	+	-	+anti Fya	-

3- Steps

2.1. ID Cards:

- Do not use cards that show signs of drying. A liquid layer should appear on top of the gel in each microtube.
- Do not use cards in which the microtubes show discoloration, bubbles or crystals.
- To confirm the specificity and reactivity of the IgG gel card the manufacturer recommends that each lot be tested each day of use with known positive and negative antibody samples with the appropriate red cell. Reactivity shall be present in the positive specimen only.

2.2. QC SAMPLES

- take the samples 1 and 2 and centrifuge them for 5 minutes at 3000 rpm
- make a cell suspension in ID-Diluent 1 or 2 as appropriate, according to the ID-card being used for the patient test procedure.
- Perform the blood grouping forward and reverse, the phenotype, the antibody screening

and the direct coombs according to the ID-card being used for the patient test procedure.

2.3. Interpretation of the results:

- Compare the reactions and the results obtained with those in the table below
- If the reactions results do not correspond to those of the table, the working procedures should be verified along with routine test methods and materials used.
- The necessary corrective action should be taken and the tests repeated.

RESULTS			A	B	AB	D	CD E	ct l	C	C w	c	E	e	K	IAT	DAT
1	A neg	ccddee	+	-	+	-	-	-	-	-	+	-	+	+	+ anti D	-
2	B +	CcDEe	-	+	+	+	+	-	+	-	+	+	+	-	+anti Fya	-

II-3- IH-QC Modular System

IH-QC tubes are intended to control the ID-System manually and/or with instruments for the determination of the ABO system, Rh (RH) system, Kell (KEL) system, and/or further immunohematology tests as listed in table 1

Table 1

Analysis, intended use	IH-QC1	IH-QC2
ABO forward and/or reverse grouping	X	X
RhD typing	X	X
Rh/K phenotyping	X	X
Antibody Screening / Identification, Indirect Antiglobulin Test (IAT)	X	X
Antibody Screening / Identification, 2 stage papain technique	X	X
Crossmatch, Indirect Antiglobulin Test (IAT)	X	X
Direct Antiglobulin Test (DAT)	X	X
RhD typing and anti-D for weak D confirmation		

REAGENT CHARACTERISTICS

Table 2	ABO	RH	K	FY	Antibodies		DAT
IH-QC1 	A ₁ [ABO:1,2,3,4]	ddcc ^{ee} (rr) C* [RH:1,2,3,4,5,8]	K ⁺ [KEL:1]	N/A	Anti-B [Anti-ABO2]	Anti-D 0.05 IU/ml [Anti-RH1]	Neg
IH-QC2 	B [ABO:1,2,3]	DCcEe (R ₁ R ₂) C* [RH:1,2,3,4,5,8]	K ⁻ [KEL:1]	Fy(a-) [FY:1]	Anti-A [Anti-ABO1]	Anti-Fy ^a [Anti-FY1]	Neg

TEST PROCEDURE

- Allow the ID-System reagents and IH-QC samples to reach room temperature (18–25 °C) prior to use.
- Perform the blood grouping forward and reverse, the phenotyping, the antibody screening and the direct coombs.
- Treat the IH-QC samples in exactly the same way as regular samples; e.g. in terms of centrifugation.
- After use, place the IH-QC samples back in the refrigerator at 2–8 °C.

INTERPRETATION OF THE RESULTS

- When properly stored and used according to ID-System test procedures, the IH-QC1 and IH-QC2 reagents will demonstrate the appropriate characteristics listed in the table under "REAGENT CHARACTERISTICS" and in the "Worksheet, IH-QC Modular System".
- If the results do not correspond to the chapter "REAGENT CHARACTERISTICS" and the "Worksheet, IH-QC Modular System", the test methods, working procedures, automated equipment/instruments and materials used should be checked immediately. Repeat the controls after making appropriate corrections.
- Different batches of antibody screening and identification red blood cells can give different reaction strengths with IH-QC1 and IH-QC2.

Table 1: Expected results for ABO, RhD, Rh/K, Antibody Screening/Identification, Direct Antiglobulin Test (DAT)

IH-QC tubes	ABO forward grouping			ABO reverse grouping				RhD		Rh/K						Antibody Screening/Identification		DAT	
	A	B	AB	A ₁	A ₂	B	O	RhD	D IAT	C	c	E	e	C ⁺	K	IAT	Papain 2 stage	IgG	C3b (pH)
IH-QC1	Pos	Neg	Pos	Neg	Neg	Pos	Neg	Neg		Neg	Pos	Neg	Pos	Neg	Pos	Anti-D	Anti-D	Neg	Neg
IH-QC2	Neg	Pos	Pos	Pos	Pos	Neg	Neg	Pos		Pos	Pos	Pos	Pos	Neg	Neg	Anti-Fy ^a	Neg	Neg	Neg
IH-QC3	Pos	Pos	Pos	Neg	Neg	Neg	Neg	Pos		Pos	Neg	Neg	Pos	Neg	Neg	Anti-c	Anti-c	Neg	Neg
IH-QC4	Neg	Neg	Neg	Pos	Pos	Pos	Neg	Pos		Neg	Pos	Pos	Neg	Neg	Neg	Anti-K		Neg	Neg
IH-QC5	Pos	Neg	Pos	Neg	Neg	Pos	Neg	Pos		Pos	Pos	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg
IH-QC6								Pos	Pos									Neg	Neg
IH-QC7																		Pos	Neg
IH-QC8																		Neg	Pos

Expected results for ABO, RhD, Rh/K, Antibody Screening/Identification, Direct Antiglobulin Test (DAT)
Erwartete Ergebnisse ABO, RhD, Rh/K, Antikörperauswahl (Sucht) Identifikation (Id), direkter Antiglobulin Test (DAT)
Résultats attendus ABO, RhD, Rh/K, Dépistage/identification d'anticorps, test direct à l'antiglobuline (TDA)
Resultados esperados ABO, RhD, Rh/K, Screening/identificación anticorpos, test de Coombs directo (DAT)
Resultados esperados ABO, RhD, Rh/K, Escrutinio de anticorpos/identificación, prueba de antiglobulina directa (C3)
Resultados esperados ABO, RhD, Rh/K, Detecção/identificação de anticorpos, Teste de antiglobulina directa (TAD)

IH-QC tubes
IH-QC Röhrchen
IH-QC tubes
IH-QC provette
IH-QC tubes
IH-QC tubes

ABO forward grouping
ABO Blutgruppenbestimmung
ABO sérotype gélules
ABO diretto
ABO hemático
ABO hemático

ABO reverse grouping
ABO Serumgegruppierung
ABO sérotype serique
ABO indiretto
ABO serico
ABO reversa

Indirect Antiglobulin Test (IAT)
Indirekter Antiglobulin Test (IAT)
Test indirect à l'antiglobuline (TIA)
Test de Coombs indirecte (ATI)
Prova de antiglobulina indirecta (AI)
Prova de antiglobulina indirecta (AI)

Pages 2 stage
2 Stufen Papartechnik
Papaina a 2 etapas
Papaina a 2 etapas
Papaina a 2 etapas
Papaina a 2 etapas

Table 2: Expected results in Indirect Antiglobulin Test (IAT) for ABO compatible crossmatches

PLASMA	CELLS			
	IH-QC1	IH-QC2	IH-QC3	IH-QC4
IH-QC1			Pos (incompatible)	Pos (incompatible)
IH-QC2	Pos (incompatible)	Pos (incompatible)	Pos (incompatible)	Pos (incompatible)
IH-QC3	Neg (compatible)		Neg (compatible)	

Expected results in Indirect Antiglobulin Test (IAT) for ABO compatible crossmatches
Erwartete Ergebnisse im indirekten Antiglobulin Test (IAT) für ABO-kompatible Kreuzproben
Résultats attendus dans le cadre de l'épreuve de compatibilité, test indirect à l'antiglobuline (TIA)
Resultados esperados para pruebas cruzadas ABO compatibles, en test de Coombs indirecto (TCI)
Resultados en la prueba de antiglobulina indirecta (AI) para pruebas cruzadas ABO compatibles
Resultados da prova de antiglobulina indirecta (AI) para provas de compatibilidade ABO compatíveis

Cells
Zellen
Cellules
Ermaze
Hematies
Células

Incompatible
Inkompatibel
Incompatibile
Incompatibile
Incompatibile
Incompatível

Compatible
Kompatibel
Compatibile
Compatibile
Compatibile
Compatível

III- QUALITY CONTROL FOR TANGO OPTIMO MACHINE

- Control set QC contains test erythrocytes with defined antigen pattern for ABO, Rh D, phenotype CcEe and Kell.
- Control set QC contains serum with negative and positive antibody screening.

RESULTS			ABS
QC-1-550	A+	CCDee K+	-
QC-2-551	B+	CcDEe Kneg	-
QC-3-552	O+	ccDEE Kneg	-
QC-4-553	AB NEG	Cc D Ee Kneg	-
QC-5-554			POS P1 P2

Procedure

- Place the control samples in a C- rack
- The control samples are identified by the TANGO optimo machine via their barcodes
- Click start
- The results are compared to the table above
- If any discrepancy is found, analysis for that should be performed.
- The results are validated and printed and kept in the file of Blood grouping.

IV- QUALITY CONTROL FOR ORTHO-VISION MACHINE

- Control set QC contains test erythrocytes and plasma with defined antigen pattern for ABO, Rh D, phenotype CcEe and Kell and for antibody screening.

RESULTS			ABS
Vial 1	AB+	CcDEe	NEG
Vial 2	O+	CCDee K+	Anti c
Vial 3	A+	ccDEE	Anti Fya
Vial 4	B NEG	ccee Kneg	Anti D (0.1 IU/ ML)

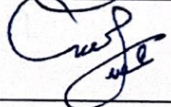
Procedure

- Place the control samples in a blue rack
- The control samples are identified by the ORTHO VISION machine via their barcodes
- Press Run QC job
- The results are compared to the table above
- If any discrepancy is found, analysis for that should be performed.
- The results are validated and printed and kept in the file of Blood grouping.

08. Reference

Technical Manual of the American Association of Blood Banks.

Preparation, Reviewing & Approval Box

	NAME	POSITION	SIGN & STAMP	DATE
Prepared By	Dr RAJA NACER SASSI	Head of Blood Bank		16/8/1440
Reviewed By	Dr. IBRAHIM AWADH	Lab & B.Bank HOD		16/8/1440
Document Reviewed By	Ms. SADIAH ALMAHMOUDI	TQM Director		18/8/1440
Reviewed By	Dr. AGEEL ALGANIMI	Medical Director		18/8/1440
Approved By	Dr. ABDULLAH ALJABRI	Hospital Director		18/8/1440

